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16444

Customer No.: 07278

Docket No.: 20052/1200517-US3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Randolph J. Noelle, et al.

Serial No.: 09/467,317

Filed: December 20, 1999

For: USE OF ANTIBODIES THAT SPECIFICALLY BIND CD40CR
(CD40 LIGAND) TO INHIBIT HUMORAL IMMUNITY

August 13, 2004

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☒ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made

the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☒ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.).

- ☐ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

[SERIAL NO. & FILING DATE].

Applicant identifies these documents by attaching hereto copies of the forms PTO-892 and PTO/SB08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Document(s) _____ are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- ☐ A concise explanation of the relevance of document(s) _____ is found in the attached search report (see MPEP § 609 A(3)x).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

☒ 5. Other information being provided for the examiner's consideration follows:
An International Search Report, dated June 30, 2004, which issued during the prosecution of European Patent Application No. EP 99 91 5237.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

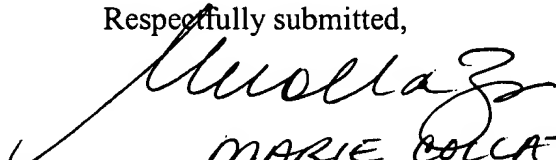
Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

(1) U.S. Patent Application Serial No _____, filed _____.

Early and favorable consideration is earnestly solicited.

August 13, 2004

Respectfully submitted,


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Attorney for Applicant(s)

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Application No. (if known): 09/467,317

Attorney Docket No.: 20052/1200517-US3

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. _____ in an envelope addressed to:

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B.W. Lee

Signature

B.W. LEE

Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Information Disclosure Statement (4 pages)

PTO SB/08 (1 page)

12 Documents

Copy of June 30, 2004 International Search Report

Return Postcard

Check No. 5869 in the Amount of \$180.00

Substitute for form 1449A/B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	09/467,317
				Filing Date	December 20, 1999
				First Named Inventor	Randolph J. Noelle
				Art Unit	1644
				Examiner Name	P. Gambel
Sheet	1	of	1	Attorney Docket Number	20052/1200517-US3

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-5,833,987-B1	11-10-1998	Noelle et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	2	WO-97/17446-A2	05-15-1997	Idec Pharmaceutical Corporation		
	3	WO-98/30240-A1	07-16-1998	Biogen, Inc.		
	4	EP-0 555 880-A2	08-18-1993	Bristol-Myers Squibb Company		
	5	WO-98/39026-A2	09-11-1998	Biogen, Inc.		
	6	WO-99/00143-A1	01-07-1999	Biogen, Inc.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	7	C. Mohan et al. "Interaction Between CD40 and Its Ligand gp39 in the Development of Murine Lupus Nephritis," Journal of Immunology, Vol. 154, No. 3, 1995, pages 1470-1480, XP002062342.	
	8	G. Early et al.: "Anti-CD40 Ligand Antibody Treatment Prevents the Development of Lupus-Like Nephritis in a Subset of New Zealand Black x New Zealand White Mice," Journal of Immunology, Vol. 157, No. 7, 1 October 1996, pages 3159-3164, XP002080042.	
	9	C. van Kooten et al.: "Functions of CD40 on B cells, dendritic cells and other cells," Current Opinion in Immunology, Current Biology Ltd., Vol. 9, No. 3, June 1997, pages 330-337, XP004313522.	
	10	Desai-Mehta, A., et al., "Hyperexpression of CD40 ligand by B and T cells in human lupus and its role in pathogenic autoantibody production", Journal of Clinical Investigation, Vol. 9, No. 97, May 1, 1996, pp. 2063-2073.	
	11	Noelle, Randolph J., et al., "A 39-kDa protein on activated helper T cells binds to CD40 and transduces the signal for cognate activation of B cells", Proceedings of the National Academy of Sciences of USA, Vol. 89, July 1992, pp. 6550-6554.	
	12	Gray, David, et al., "Memory B cell development but not germinal center formation is impaired by in vivo blockade of CD40-CD40 ligand interaction", Journal of Experimental Medicine, Vol. 180, No. 1, 1994, pp. 141-155.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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